

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Riechers et al.	Examiner:	N/A
Serial No.: 08/809,699	Group Art Unit No.:	1611
Patent No.: 5,932,730		
Filing Date: March 27, 1997	Confirmation No. :	7925
Issue Date: August 3, 1999		

For:

Carboxylic Acid Derivatives, Their Preparation and Use

**PETITION UNDER 37 CFR §1.181 REQUESTING RECONSIDERATION OF THE DETERMINATION OF THE LENGTH OF THE PATENT TERM EXTENSION UNDER 37 CFR §1.710 FOR US PATENT NO. 5,932,730**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Final Determination and Requirement for Election mailed in the above patent on February 23, 2010 (hereinafter “Notice”), Applicant hereby petitions under 37 CFR §1.181 for reconsideration of the determination of the length of the patent term extension for US Patent No. 5,932,730.

Statement of Facts

US Patent No. 5,932,730 contains claims which cover the human drug product LETARIS® (ambrisentan). The FDA published its determination as to the regulatory review period for LETARIS® in the Federal Register, Vol. 74, No. 26, pp. 6635-36 on February 10, 2009 (See attached Exhibit A). Specifically, the FDA determined that the applicable regulatory review period for LETARIS® was 1,871 days. Of this time, 1,691 days occurred during the Testing Phase of the regulatory review period, while 180 days occurred during the Approval Phase.

According to the Notice, the period of extension for the above application was calculated as follows:

$$\text{Period of Extension} = \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase}$$

$$= \frac{1}{2} (1691-0) + 180$$

$$= 1025 \text{ days (2.8 years)}$$

Points to be Reviewed

Applicant requests that the Director review and reconsider the 1025 day period of extension calculated by the Office in the Notice. Specifically, Applicant submits that an error was made in the above calculation and that the length of the extension should be 1026 days (not 1025 days as recited in the Notice). According to 37 CFR §1.175 (d)(1)(iii) (attached herewith as Exhibit B), when one-half of the Testing Phase (845.5 days) is subtracted from the total regulatory review period (1,871 days), half days (namely, the  $\frac{1}{2}$  or 0.5 of the day) are ignored for the purposes of the subtraction.. Therefore, the calculation is  $1,871 \text{ days} - 845 \text{ days} = 1026 \text{ days}$ . Applicant herewith encloses in Exhibit C a sheet showing the correct patent term extension calculation for the Director's convenience.

Action Requested

In view of the aforementioned arguments, Applicant herewith submits that the term extended for US Patent No. 5,932,730 should be **1026** days, not 1025 days as indicated in the Notice. Applicant requests that the Director correct the error made by the Office in calculating the period of extension for LETARIS®. Specifically, Applicant requests that said period of extension be corrected from 1025 days to **1026** days.

Petition Fee

If any petition fee is due or owing as a result of the filing of this paper, authorization is given to charge any such petition fee as well as any other fees incurred in connection with this patent and this paper with deposit account number 50-1662.

**Polsinelli Shughart**

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Respectfully submitted,

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March 22, 2010

Date:

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